THE GLUTAMATE ASSOCIATION
UNITED STATES

April 4, 2003

BY ELECTRONIC AND FIRST CLASS MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0276 (Registration)

The Glutamate Association (TGA) welcomes this opportunity to submit comments on the aforementioned proposed rule that would implement the food facility registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act" or "Act"). TGA is the trade association that represents manufacturers and users of monosodium glutamate (MSG). As members of the food industry, our member companies will be impacted by this proposed rule.

TGA supports FDA in its efforts to implement this very important provision of the Act. Although we are supportive of many provisions of the proposed rule, we are concerned that certain provisions have the potential to be unduly restrictive and overly burdensome. We believe that minor modifications to the proposed rule would provide more flexibility while allowing the agency to collect the information that it needs to register food establishments.

The Bioterrorism Act requires all facilities that manufacture, process, pack or hold food to register with the agency, with certain exceptions. TGA offers the following comments on the agency's proposed implementation of this requirement.

- FDA should clarify that vehicles/vessels that hold food for transportation purposes would not be required to register with FDA. The proposal would define food facilities to include "a mobile facility traveling to multiple

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locations that . . . holds food for consumption in the U.S." "Holding" would be defined as the "storage of food." Although FDA has stated that it does not intend for the registration requirement to require carriers to register with FDA, it is not clear from the face of the proposal; nor did FDA clarify this in the preamble to the proposal.

- FDA's proposal would require the submission of general product code categories for all foods in a registered facility. The Bioterrorism Act would allow FDA to require the submission of this information "when determined necessary by the Secretary." We do not believe that the agency has demonstrated that product category information is needed to implement the registration requirements of the Bioterrorism Act. Moreover, this proposed requirement would force manufacturers to spend significant time and resources identifying and then inputting into the FDA system the myriad of product codes manufactured in facilities. There are many manufacturing facilities that manufacture a wide variety of products and the type of products manufactured by that facility are subject to change over time. Requiring companies to identify the product categories of foods manufactured in each facility would impose a significant burden on the industry with limited corresponding benefit to FDA. We encourage FDA to eliminate the requirement that manufacturers would need to identify the product categories of foods manufactured in each facility. If the agency believes that it must have detailed information on the type of foods manufactured at certain facilities, the agency should, at a minimum, revise the registration form to allow a company submitting registrations on behalf of numerous facilities to indicate that the company's facilities, when considered together, manufacture/process, pack, and/or hold products in "most/all food product categories."

- FDA could ease significantly the burden of collecting registration information by allowing transmission of electronic data files. This would allow a company operating to submit a single file encompassing the required registration information for all facilities it owns, operates, or for which it is acting as an agent. The ability to submit registration data via transmission of electronic files (e.g., Microsoft Excel), in lieu of interactive data entry, would streamline the administrative burden associated with the new regulation.

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TGA once again commends the agency on its efforts on establishing final regulations that would implement the registration provisions of the Bioterrorism Act. We encourage the agency to consider these and the other comments as it finalizes the final regulations.

TGA would be more than happy to provide additional information if it would be of assistance to the agency.

Sincerely,

Martin J. Hahn
Executive Director

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